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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,319	10/26/2001	Michael R.S. Hill	P-10124.00	3335
27581	7590	03/09/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			GROPEZA, FRANCES P	
			ART. NO.	PAPER NUMBER

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/035,319

Applicant(s)

HILL ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/6/06 & 11/7/05 (RCE & Amendment).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination/ Response

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 1/6/06 has been entered.

2. In the response of 6/29/05, the Applicant amended the claims hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

3. Claims 20, 22-24, 26 and 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartlaub (US 6134470). Hartlaub discloses a method and device with physiological sensors (342), sensor controls (340), neural stimulator (272) and controllers (270, 244) to detect the precursors to tachyarrhythmias and respond with stimulation of the spinal cord/ spinal roots, pacing therapy and/or a drug delivery system. The therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The spinal cord generator is activated for predetermined time periods, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The results of past stimulation are used to perform future stimulation (abstract; figures 1, 2; col. 1 @ 42-52; col. 2 @ 3-15 and 40-53;

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col. 4 @ 35-47; col. 4 @ 56 – col. 5 @ 7; col. 6 @ 25-54 col. 7 @ 47-61;

col. 8 @ 66 – col. 9 @ 20; col. 9 @ 53-67; col. 11 @ 24-65; col. 12 @ 19-25; col. 13 @ 4-34).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Hartlaub discloses the use of the device with the excitable neural tissue of a portion of the spine, the spinal cord (col. 1 @ 5-9; col. 4 @ 35-47). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Hartlaub discloses closed loop control of the stimulation system (abstract; col. 1 @ 45-52; col. 6 @ 44-54; col. 9 @ 15-19).

As to claims 21, 31 and 32 and a drug dispensing apparatus/ means for dispensing biologically-active agents, Hartlaub teaches use of a drug dispenser (col. 5 @ 3-7) and incorporates by reference (col. 5 @ 3-13) US 5220917 to Cammilli et al. who teaches a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the medicament via a catheter (col. 1 @ 62-68).

Claim Rejections - 35 USC § 103

4. Claims 20-22, 26, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel et al. (US 5199428) in view of Cammilli et al. (US 5220917).

Obel et al. disclose a nerve stimulator (108) and pacing therapy (104) to respond to a physiological parameter (pH and SO₂) which provides “a meaningful predictor of ischemia” and potential arrhythmias to the controller (100). The therapy is provided for “a meaningful predictor of ischemia” and potential arrhythmias, hence the system anticipates the occurrence of a cardiac insult. A patient activation mechanism is taught (abstract; figure 2; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25; col. 10 @ 3-5).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Obel et al. discloses the use of the device with the excitable neural tissue of a portion of the spine, the “other effective nerves” read as the ganglion stellate associated with the Autonomic Nervous System (col. 1 @ 9-13; col. 3 @ 8-19). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and a closed loop control of the stimulation system, Obel et al. discloses a closed loop control of the stimulation system (abstract; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25).

As discussed in the previous four paragraphs of this action, Obel et al. disclose the claimed invention except for a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the drugs via a catheter.

Cammilli et al. teach drug delivery using a drug delivery device that delivers the medicament via a catheter for the purpose of treating ventricular fibrillation. It would have been

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obvious to one having ordinary skill in the art at the time of the invention to have used a drug delivery device that delivers the drugs via a catheter in the Sweeney et al. system in order to use a proven means of cardiac therapy that can effectively treat cardiac dysfunction using an alternate means to electrical stimulation (col.1 @ 53-68).

5. Claims 20, 22-26, 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al. (US 6272377) in view of Cammilli et al. (US 5220917).

Sweeney et al. disclose a cardiac management system that predicts arrhythmias, based on physiological parameter(s), and treats the anticipated occurrence of a cardiac insult with neural stimulation. A warning is provided to the patient that an arrhythmia has been predicted (abstract; col. 1 @ 7-11; col. 2 @ 11-16, 39-45 and 58-66; col. 4 @ 61 – col. 5 @ 20; col. 8 @ 23-55; col. 9 @ 3-32 and 45-62).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Sweeney et al. discloses the use of the device with the excitable neural tissue of a portion of the spine, specifically the stellate ganglion (col. 8 @ 49-53). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Sweeney et al. discloses closed loop control of the stimulation system (abstract; col. 4 @ 61 – col. 5 @ 20).

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As to claims 21, 31 and 32 and a drug dispensing apparatus/ means for dispensing biologically-active agents, Sweeney et al. teach the delivery of drugs (col. 22 @ 16-35) as therapy for arrhythmias.

As discussed in the previous five paragraphs of this action, Sweeney et al. disclose the claimed invention except for a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the drugs via a catheter.

Cammilli et al. teach drug delivery using a drug delivery device that delivers the medicament via a catheter for the purpose of treating ventricular fibrillation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the drugs via a catheter in the Sweeney et al. system in order to use a proven means of cardiac therapy that can effectively treat cardiac dysfunction using an alternate means to electrical stimulation (col. 1 @ 53-68).

6. Claims 20, 22-24, 26-28 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmstrom et al. (EP 0 688 577 A1) in view of Cammilli et al (US 5220917).

Holmstrom et al. disclose a device for impending supraventricular heart therapy comprising an implantable cardiac and neural electrode system to sense and stimulate (23), a

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detection block (5) of cardiac (51) and neural (53) sensing circuits to sense the physiological parameter(s), a neural stimulation circuit (9), a control circuit (13), and a pacing circuit (7) (figure 1). The therapy is provided for impending ventricular tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The neural generator includes a time control unit (92) that is programmed, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The stimulator can be used externally with external and internal electrodes, read as positioned proximate an external body surface and positioned subcutaneously, respectively (abstract; figure 1; col. 3 @ 6-27 and 37-50; col. 4 @ 1-50; col. 5 @ 10-39; col. 7 @ 43-52; col. 8 @ 10-56; col. 9 @ 10-13 and 40-44).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Holmstrom et al. discloses the use of the device with excitable neural tissue of a portion of the spine, specifically the ganglion stellate (col. 3 @ 6-27; col. 7 @ 50). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Holmstrom et al. discloses closed loop control of the stimulation system (col. 4 @ 29-50; col. 5 @ 10-39; col. 6 @ 54 – col. 7 @ 7; col. 7 @ 53 – col. 8 @ 56).

As discussed in the previous four paragraphs of this action, Holmstrom et al. disclose the claimed invention except for a drug dispensing apparatus/ means for dispensing biologically-active agents.

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Cammilli et al. teach drug delivery using a drug delivery device that delivers the medicament via a catheter for the purpose of treating ventricular fibrillation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a drug dispensing apparatus/ means for dispensing biologically-active agents that delivers the drugs via a catheter in the Holmstrom et al. system in order to use a proven means of cardiac therapy that can effectively treat cardiac dysfunction using an alternate means to electrical stimulation (col. 1 @ 53-68).

Statutory Basis

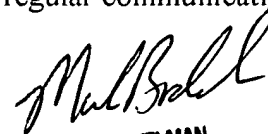
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3766

JPO
3/6/06


MARK BOCKELMAN
PRIMARY EXAMINER